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EXAMINER	
LIU, SUE XU	
ART UNIT	**PAPER NUMBER**
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/963,698	BARANY ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-112 and 148* is/are pending in the application.

4a) Of the above claim(s) *98-108 and 110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-97,109,111,112 and 148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 1-88 and 113-147 have been canceled.

Claim 148 has been added as filed on 11/30/06.

Claims 89-112 and 148 are currently pending

Claims 98-108, and 110 have been withdrawn;

Claims 89-97, 109, 111, 112 and 148 are being examined in this application

Election/Restrictions

2. Claims 98-108 (dependent on claim 99), 110 are withdrawn from further consideration as acknowledged in the previous office actions.

Priority

3. This application is a divisional of application 08/794,851 (filed 2/04/1997; now US 6,852,487), which claims priority to US provisional application 60/011,359 (filed on 2/9/1996).

Information Disclosure Statement

4. The information disclosure statement filed on 11/30/2006 has been considered. See attached PTO 1449 form.

Specification

5. Applicant's submission of a substituted Abstract is acknowledged and entered.

Claim Rejections Maintained

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Lipshutz

7. Claims 89, 93 and 148 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (BioTechniques, Vol 19, No. 3, 1995, pages 442-447). The previous rejection over Claims 89 and 93 are maintained for the reasons set forth in the previous office action mailed on 9/8/03, and is incorporated herein by reference in its entirety. The rejection over Claim 148 is necessitated by applicant's amendment to the claim. For simplicity sake, only the relevant teaching of the reference to the instant Claim 148 is discussed below.

Although, the reference does not explicitly teach oligonucleotides with 16 or greater nucleotides, the reference inherently teaches the specific oligonucleotide length. The reference

teaches "any set of probes of length k or less can be (probes in different synthesis sites can be different lengths)..." (p. 443, right col., para 2), and the set of all 4^k length k oligonucleotides (k-mers) can be generated in 4k synthesis cycles. Thus, if k equal to 6 or larger, the oligomers taught by the reference would have nucleotides 16 or greater.

Discussion and Answer to Argument

8. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue "Lipshutz neither discloses nor suggests forming an array of a plurality of capture oligonucleotides on the solid support by a series of cycles, carried out repeatedly at each array position, of activating selected array positions for attachment of multimer nucleotides and attaching multimer nucleotides at activated array positions". (Reply, p. 8, last para). Applicants also state "Simply stated, repeatedly adding one nucleoside to an array at a time is not the same as repeatedly putting a multimer on the array". (Reply, p. 9, para 1).

As stated by applicants (Reply, p. 8, para 4), Lipshutz teaches "a method ... to create high-density arrays of oligonucleotide probes" (emphasis added), which read on the "capture oligonucleotides" of the instant claims as well as the "capture oligonucleotides" of the above cited argument. Applicants also state that Lipshutz teaches the synthesis of the oligonucleotide is through "repeated" "chemical cycle" (Reply, p. 8, para 4), which reads on the "series of cycles", and "carried out repeatedly at each array position" of the instant claims.

Contrary to applicant's assertion, Lipshutz does teach attaching "capture oligonucleotides" and/or "multimer nucleotides". Lipshutz teaches simultaneous synthesis of oligomers (read on multimers because oligomers are comprised of multiple nucleotides by definition) as shown in Figure 1 of the reference. This also reads on attaching multimers to solid substrate because the end products of the combinatorial oligonucleotide synthesis on a solid substrate are attached oligomers (i.e. "capture oligonucleotides" or "multimers" or "multimer nucleotides"). The reference further teaches, as an example, a set of all 15-mers (i.e. oligonucleotides with 15 nucleotides) can be synthesized in 60 cycles under 10 hours (see pg 443, bridging para. of middle and right cols.).

Applicants further argue the Lipshutz reference "neither discloses nor suggests using multimer nucleotides which are selected for attachment so that the capture oligonucleotides formed hybridize to complementary oligonucleotides under uniform hybridization conditions, as required by the instant claims". (Reply, p. 9, para 2).

The phrase of "the multimer nucleotides are selected for attachment so that the capture oligonucleotides formed one the array hybridize with complementary oligonucleotides target sequences under uniform hybridization conditions" is a recitation of intended use or inherent property of the said "multimer nucleotides" or "capture oligonucleotides". A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative

difference as compared to the prior art. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and In re Otto, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicants further assert that the recited intended use of the array does provide a structural distinction. (Reply, pp. 9+).

The instant claim does not specify the target sequence, which can be any sequence. Hybridization between probes and target sequences depends mainly on the specific nucleic acid sequences. As it is recited in the instant claims (e.g. Claim 89) and also as pointed out by applicants, "the capture oligonucleotides ... hybridize with complementary oligonucleotide target sequences" under uniform hybridization conditions".

Applicants argue that the "office action is incorrect in stating that the target sequences can be any sequence. As is clear from the language of the claims, the target sequences are those complementary to claimed capture oligonucleotides" (Reply, p. 10, para 3). Applicants appear to present a circular argument regarding the structural requirement of the "capture oligonucleotides". On the one hand, applicants are asserting the structure of the "capture oligonucleotides" are specified by their complementary "target sequences" (Reply, p. 10, para 2). However, applicants also argue that the "target sequences" themselves are structurally limited by the sequences of the "capture oligonucleotides".

As discussed previously, neither the instant specification nor the claims provide structural limitation for the claimed "target sequences" or "capture oligonucleotides". There is also no showing that the recited "capture oligonucleotides" and "multimer nucleotides" are structurally (sequentially) different from the probes of the Lipshutz reference. The term "target sequences"

recited in the instant claims is very broad and encompasses any sequence. The probes taught by the reference can hybridize to the target sequences under a given hybridization condition.

Furthermore, applicants' arguments regarding the "uniform hybridization conditions" (Reply, p. 10, para 2) are also not persuasive. Neither the instant specification nor the claims specify what conditions are "uniform hybridization conditions". A hybridization reaction on a particular array is carried out under one (or uniform) condition, because the array is completely immersed in the hybridization reaction solution, as discussed in Lipshutz reference (pp. 443-444, bridging col.), and the instant specification (e.g. p. 13, lines 29+). Thus, any condition for hybridization using an array for hybridizing with any target sequence may be viewed as "uniform hybridization conditions".

Therefore, the recitation of intended use of hybridization with target sequence does not offer any additional structural limitation for the instantly claimed invention, and also does not demonstrate a structural difference from the reference's teaching.

Furthermore, the reference teaches using the generated array to hybridize with target nucleic acids (see pg 443, last para.), which reads on the intended use recited in the instant claim. Thus, the oligonucleotides on the array as taught by the Lipshutz reference are complementary to the "target sequences" that the oligonucleotides are designed to hybridize.

Applicants further argue that "the probes in Lipshutz's array carry the burden of both detecting a target nucleic acid and generating a signal correlated to detection of the target". (Reply, p. 9. para 2).

The purpose of the probes recited in the reference is irrelevant, because the method of generating the array of probes is not structurally different from the method claimed in the instant application.

Applicants further argue the intended use of the array for hybridization under uniform hybridization conditions. For support of the argument, applicant states "designing a plurality of capture probes to detect and signal detection of a plurality of different nucleic acid targets at one time on a single array (i.e. under uniform hybridization conditions) is a difficult task using Lipshutz's technology." (Reply, p. 9, para 2)

It is known in the art, one of the major purposes of generating an array is to using a single chip to detect samples under one condition. As taught by Lipshutz et al, target sample is hybridized to the probes under a fixed set of hybridization conditions (see pg 443, last para. and pg444, left col.).

Applicants also cited an example to argue the distinction between the reference's teaching and the instantly claimed invention. (Reply, p. 9, para 3).

The recited LDR in the example is not claimed feature in the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tetramer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants further argue one of the advantage that distinguish the instantly claimed invention from the reference's teaching is "the formed arrays can permit detection of a target separately from signaling such detection". (Reply, p. 11, para 1).

Applicants seem to state that the advantage of the instantly claimed array is that the target can be detected without detecting the said target. The term "detection" by definition requires some kind of signaling so that the actual "detection" can be achieved.

Furthermore, the purported "advantage" is not a feature cited in the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "detection of a target separately from signaling such detection") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Fodor et al (1993)

9. Claims 89 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al (Nature, vol. 364, August 1993, pages 555-556) for the reasons set forth in the previous office action mailed on 9/8/03.

Discussion and Answer to Argument

10. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the Fodor reference with the same argument as the traversal over the Lipshutz reference.

Applicants are respectively directed to the above discussion under Lipshutz for answer to arguments. Fodor teaches synthesizing oligonucleotides at specific locations or position on an array, which reads on linking oligonucleotides to a substrate surface, as recited in the instant specification. Similar to the discussion over the Lipshutz reference, applicants have not demonstrated any structurally distinction of the claimed invention over the reference's teaching.

Southern et al

11. Claims 89-93, 96-97, 109, 111 and 148 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,700,637 (SOUTHERN) (the reference provided by applicants in the IDS filed on 8/9/04. The previous rejection over Claims 89-93, 96-97, 109, 111 are maintained for the reasons set forth in the previous office action mailed on 9/8/03, and is incorporated herein by reference in its entirety. The rejection over Claim 148 is necessitated by applicant's amendment to the claim. For simplicity sake, only the relevant teaching of the reference to the instant Claim 148 is discussed below.

The reference teaches generating probes with various lengths, for example, 17 nucleotides long (col. 5, lines 5+), which reads on the length as recited in the instant claim 148.

Discussion and Answer to Argument

12. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the Southern reference with the same argument as the traversal over the Lipshutz reference.

Applicants are respectively directed to the above discussion under Lipshutz for answer to arguments. In addition, applicants argue that the oligonucleotides forming the array are only disclosed by Southern et al to be formed from conventional nucleotides. (Reply, p. 12, para 1). However, applicants do not elaborate on how the disclosed "conventional nucleotides" are different from the nucleotides recited in the instant claims. Therefore, applicants have not demonstrated a structural difference between the claimed invention and the reference's teaching.

Chee et al

13. Claims 89, 91, 93, 96, 111 and 148 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,832 (Chee et al) (reference provided by applicants in IDS filed on 4/26/04). The previous rejection over Claims 89, 91, 93, 96 and 111 are maintained for the reasons set forth in the previous office action mailed on 9/8/03, and is incorporated herein by reference in its entirety. The rejection over Claim 148 is necessitated by applicant's amendment to the claim. For simplicity sake, only the relevant teaching of the reference to the instant Claim 148 is discussed below.

The reference teaches generating probes with various lengths, for example, between 14 to 18 nucleotides (col. 6, line 5), which reads on the length as recited in the instant claim 148.

Discussion and Answer to Argument

14. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the Southern reference with the same argument as the traversal over the Lipshutz reference.

Applicants are respectively directed to the above discussion under Lipshutz for answer to arguments. Applicants argue that "the oligonucleotide probes used on the subject chips of Chee do not constitute capture probes in accordance with the present invention where the capture olignucleotides on the array hybridize with complementary oligonucleotide target sequences under uniform hybridization conditions." (Reply, p. 12, para 3). However, applicants have not demonstrated a structural difference between the claimed invention and the reference's teaching.

Fodor (Patent)

15. Claims 89-97, 109, 111, 112 and 148 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,510,270 (Fodor et al). The previous rejection over Claims 89-97, 109 and 111-112 are maintained for the reasons set forth in the previous office action mailed on 9/8/03, and is incorporated herein by reference in its entirety. The rejection over Claim 148 is

necessitated by applicant's amendment to the claim. For simplicity sake, only the relevant teaching of the reference to the instant Claim 148 is discussed below.

The reference teaches generating probes with various lengths, for examples, between 2-20 nucleotides (cols. 9-10. bridging para), which reads on the length as recited in the instant claim 148.

Discussion and Answer to Argument

16. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the Fodor (patent) reference with the same argument as the traversal over the Lipshutz reference.

Applicants are respectively directed to the above discussion under Lipshutz for answer to arguments. Applicants generally argue that Fodor (patent) "neither discloses nor suggests forming an array using capture oligonucleotides..." (Reply, pp. 12-13, bridging para). However, applicants have not demonstrated a specific structural difference between the claimed invention and the reference's teaching.

Holmes

17. Claims 89-94, 96-97, 109, 111, 112 and 148 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,527,681 (HOLMES et al). The previous rejection over Claims 89-94, 96-97, 109, and 111-112 are maintained for the reasons set forth in the previous office action

mailed on 9/8/03, and is incorporated herein by reference in its entirety. The rejection over Claim 148 is necessitated by applicant's amendment to the claim. For simplicity sake, only the relevant teaching of the reference to the instant Claim 148 is discussed below.

The reference teaches generating probes with various lengths, for examples, between 2-20 nucleotides (cols. 9. lines 20+), which reads on the length as recited in the instant claim 148.

Discussion and Answer to Argument

18. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the Holmes reference with the same argument as the traversal over the Lipshutz reference.

Applicants are respectively directed to the above discussion under Lipshutz for answer to arguments. Applicants argue that Holmes "neither discloses nor suggests forming an array using capture oligonucleotides..." (Reply, p. 13, para 3). However, applicants have not demonstrated a structural difference between the claimed invention and the reference's teaching.

Claim Rejections - 35 USC § 112

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 89-97, 109, 111, 112 and 148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection over Claims 89-97, 109, 111, and 112 is maintained for the reasons of record as set forth in the Office action, mailed 5/30/06, at p. 11. The rejection over Claim 148 is necessitated by applicant's amendment to the claims.

Discussion and Answer to Argument

21. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the claim amendments would overcome the outstanding rejection under 35 USC §112 2nd paragraph. (Reply, p. 13, last para).

Applicant's amendment to the claims have overcome some issues under 35 USC §112 2nd paragraph, however, the claim amendment does not overcome the entire rejection as set forth in the previous Office action. The rejection is rewritten below for clarification of the record:

The claim language of Claim 89 is convoluted and confusing, and therefore renders the said claim and its dependent claims indefinite. For example, the claim recites "forming an array of a plurality of capture oligonucleotides on the solid support by a series of cycles, carried out repeatedly at each array position, of activating selected array positions for attachment of multimer nucleotides and attaching multimer nucleotides at activated array positions, wherein the multimer nucleotides are selected for attachment so that the capture oligonucleotides formed on the array hybridize with complementary oligonucleotide target sequences under uniform hybridization conditions, wherein the multimer is formed from multiple nucleotides linked

together". (emphasis added). It is not clear what part of the claimed element is modifying or being modified by the underlined region.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between "capture oligonucleotides" and "multimer nucleotides". Claim 89 recites the term "multimer nucleotides", which is not clearly defined in either the claims or the specification. Claim 89 also recites the term "capture oligonucleotides". The nexus between the two terms ("capture oligonucleotides" and "multimer nucleotides') is not clearly recited in the claim. It is not clear from the claim language that the "capture oligonucleotides" and the "multimer nucleotides" are the same entities, and their relationship as used in the claimed method.

Claim 89 recites the limitation "the capture oligonucleotides" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 109 recites the limitation "the surface". There is insufficient antecedent basis for this limitation in the claim. Claim 89 recites "surfaces" in plural, but Claim 109 recites a singular "surface". It is not clear to which "surface" Claim 109 is referring.

Claim 148 recites the limitation "the capture oligonucleotides". There is insufficient antecedent basis for this limitation in the claim.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
2/20/2007

JON EPPERSON
PRIMARY EXAMINER